EXHIBIT B

Matthew McNew Declaration

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
BLUEFIELD DIVISION

UNITED STATES OF AMERICA Plaintiff, v. SOUL VAPOR, LLC, a corporation, and AURELIUS JEFFREY, an individual, Defendants.	Civil No. 1:22-cv-00458 **DECLARATION OF MATTHEW R. MCNEW**

I, Matthew R. McNew, declare as follows:

Introduction

1. I am a Commissioned Officer of the U.S. Public Health Service ("USPHS"), at the rank of Lieutenant Commander (O-4), and serve as Consumer Safety Officer ("CSO") in the Tobacco Operations Staff ("TOS"), Office of Medical Products and Tobacco Operations, Office of Regulatory Affairs ("ORA"), United States Food and Drug Administration ("FDA"). My office is located at 412 N. Cedar Bluff Road, Suite 415, Knoxville, TN 37923.

2. I have a Bachelor of Science from East Tennessee State University, and a Master of Public Health from American Military University. At FDA, I have received training both in the classroom and on the job to become a certified investigator. The training has been in many areas including, but not limited to, the tobacco product requirements of the Federal Food, Drug, and Cosmetic Act (the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act, and FDA's tobacco product regulations. I have held a National Environmental Health Association Registered Environmental Health Specialist/Registered Sanitarian credential since November 2008.

3. Prior to joining FDA, from September 2002 until December 2003, I worked as an environmental specialist for Nuclear Fuel Services, Inc., a company that manufactures fuel material for naval nuclear reactors used in U.S. submarines and aircrafts.

4. I began my work at FDA in January 2004 as a CSO in ORA, Kansas City District Office, Lenexa, KS, and simultaneously accepted an active duty uniformed commissioned officer position with the USPHS. My responsibilities included the planning, preparation, and execution of establishment inspections for various FDA-regulated program areas while completing required FDA and USPHS training. From approximately fiscal year ("FY") 2012 through FY 2014, these inspections included tobacco product manufacturer inspections.

5. In January 2018, I became a TOS investigator. As a TOS investigator, I conduct inspections of tobacco product manufacturers to assess their compliance with the Act and FDA tobacco product regulations. I collect evidentiary support for the observations I make during inspections and prepare Establishment Inspection Reports ("EIRs"), which are official records prepared by FDA investigators to document and describe our observations during inspections.

6. Altogether, I have 19 years of experience as a CSO conducting inspections within food, drug, medical devices, animal feeds, and tobacco programs. I have conducted approximately 83 investigations, 71 inspections, and 3 remote regulatory assessments of tobacco product manufacturers since I started working in the TOS.

March 2022 Inspection of Soul Vapor

7. Between March 23 and 25, 2022, I conducted an inspection (hereafter, "March 2022 inspection") of Soul Vapor, LLC ("Soul Vapor"), located at 604 Thorn Street, Princeton, WV 24740-3757 (hereafter, "Defendants' establishment"). I was the lead investigator. Investigator Young Kim also assisted in the inspection by, among other things, collecting

documents, taking photographs, and conducting partial write-ups of the evidentiary documents and the EIR. A true and accurate copy of the EIR for the March 2022 inspection is attached as Exhibit ("Ex.") 1. The statements in this declaration are based upon my personal knowledge and FDA records relating to Soul Vapor and Aurelius Jeffrey (collectively, "Defendants"), including records that were collected during the March 2022 inspection or made during or following the inspection at or near the time of the event. The exhibits to this declaration are all true and accurate copies of official FDA records that are accessible to me or are in my possession. FDA makes and retains these business records in the ordinary course of its regulatory duties. These records are retained at FDA's Miami Lakes Office, 15100 NW 67th Ave., STE 400, Miami Lakes, FL 33014.

8. The March 2022 inspection was a follow-up inspection to determine whether Defendants had voluntarily corrected violations identified in a Warning Letter issued to them on May 21, 2021, by FDA's Center for Tobacco Products ("CTP"), Office of Compliance and Enforcement. A true and correct copy of the Warning Letter is available at https://perma.cc/WVX3-687B. The Warning Letter notified Defendants that they manufacture and offer for sale or distribution new tobacco products that lack required FDA authorization, including certain finished electronic nicotine delivery system ("ENDS") products under the Soul Vapor brand, and that, as a result of their lack of FDA authorization, such products are adulterated and misbranded. *Id.*

9. As explained in more detail below, during the March 2022 inspection, I documented that Defendants manufacture, sell, and distribute finished ENDS products, including finished e-liquid products, at and from Defendants' establishment. Defendants' manufacturing activities include mixing, bottling, and labeling their ENDS products.

10. On March 23, 2022, I issued a Notice of Inspection ("Form FDA-482"), to Aurelius Jeffrey. When we arrived, Mr. Jeffrey identified himself to us as the most responsible individual at the firm. A true and correct copy of the Form FDA 482 that I issued at the start of the inspection is attached to this declaration as Ex. 2.

11. During the March 2022 inspection, Soul Vapor was not manufacturing ENDS products at Defendants' establishment. However, I observed evidence of ENDS product manufacturing at Defendants' establishment, including nicotine, flavorings, bottles, labels, and equipment to manufacture ENDS products. In addition, Mr. Jeffrey told me that Soul Vapor currently manufactures ENDS products.

12. During the March 2022 inspection, Mr. Jeffrey stated that Defendants' ENDS product manufacturing includes: bottling bulk liquid nicotine at varying concentrations into 10mL bottles; and, separately, mixing flavoring(s) with propylene glycol ("PG") and vegetable glycerin ("VG"), and packaging the resulting flavoring/PG/VG blend into a 10mL, 30mL, or 120mL bottle. Mr. Jeffrey stated that Defendants do not mix the manufactured liquid nicotine and flavoring/PG/VG blends together. Mr. Jeffrey further stated that when customers purchase the manufactured liquid nicotine and flavoring/PG/VG blends separately, retail employees of Soul Vapor provide verbal instructions to the customer on properly mixing them. True and correct copies of sales invoices for ENDS products sold by Soul Vapor to customers, dated March 18, 2022 and March 25, 2022, are attached to this declaration as Exs. 3 and 4.

13. During the March 2022 inspection, Mr. Jeffrey estimated that Defendants use approximately 100 different flavors in their manufacturing of flavoring/PG/VG blends. A true and accurate copy of flavors used in flavoring/PG/VG blends provided by Mr. Jeffrey during the March 2022 inspection is attached to this declaration as Ex. 5.

14. During the March 2022 inspection, Aurelius Jeffrey confirmed that he is Soul Vapor's sole owner, and the most responsible individual at the firm. Mr. Jeffrey also told us that he oversees all business aspects for Soul Vapor and makes all business decisions for Soul Vapor, including ordering raw ingredients and materials used to manufacture ENDS products under the Soul Vapor brand.

15. During the March 2022 inspection, I observed Soul Vapor offer for retail sale to consumers finished ENDS products under the Soul Vapor brand, and finished ENDS products manufactured by others. The finished ENDS products that Soul Vapor held and offered for sale include Soul Vapor Honey Pot and Soul Vapor Peach Rings. True and accurate copies of photographs taken during the March 2022 inspection, showing the ENDS products on display at Defendants' establishment, are attached to this declaration as Ex. 6.

16. Soul Vapor purchases the nicotine that it then repackages to manufacture its liquid nicotine products from Thousand Oaks, California and Phoenix, Arizona, and has it shipped to Defendants' establishment. A true and accurate copy of the invoices for the nicotine, dated May 21, 2019 and October 29, 2021, respectively, are attached to this declaration as Exs. 7 and 8. *See also* Ex. 6 (photographs of liquid nicotine labels).

17. Soul Vapor purchases the PG and VG used to manufacture its flavoring/PG/VG blend products from Aurora, Ohio, and has them shipped to Defendants' establishment. A true and accurate copy of the invoice for the PG and VG, dated October 29, 2021, is attached to this declaration as Ex. 9.

18. On March 25, 2022, Investigator Kim and I returned to Defendants' establishment to hold a close-out meeting with Mr. Jeffrey. During that meeting, I discussed the observations with Mr. Jeffrey and again reminded him of his duty to comply with the Act. Mr. Jeffrey stated

that he believes that he no longer manufactures finished tobacco products because he no longer mixes liquid nicotine with flavorings or flavoring/PG/VG blends. Mr. Jeffrey further stated that he had not, and did not intend to, submit marketing applications for his liquid nicotine and flavoring/PG/VG blend products. Mr. Jeffrey did not promise any corrective actions that would resolve the violations at that time.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Matthew R. Mcnew -S

Digitally signed by Matthew R. Mcnew -S
Date: 2023.02.10 13:36:10 -05'00'

Matthew R. McNew
Regulatory Officer
Tobacco Operations Staff
Office of Medical Products and Tobacco Operations
Office of Regulatory Affairs
United States Food and Drug Administration

Executed on February 10, 2023

EXHIBIT B

B-1 McNew Exhibit 1 (Inspection Rpt)

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SUMMARY

(MRM)

This directed, comprehensive warning letter follow-up inspection of a tobacco manufacturing firm was conducted in accordance with a High Priority Inspection request from the Center for Tobacco Products (CTP) memorandum, dated 3/4/22 (**Attachment 3**), ORA FY22 work plans, and eNSpect operation #221645. The inspection was conducted pursuant to a CTP Warning Letter issued on 5/21/2021. The warning letter revealed that the firm manufactured and offered for sale or distribution to customers in the United States e-liquid products without a marketing authorization for Soul Vapor Honey Pot and Soul Vapor Peach Rings and/or other e-liquid products. Additional CTP requests for other potential tobacco product marketing and modified risk claims issues were reviewed and verified. This is the initial inspection of this firm.

The current inspection revealed that the firm inactivated its registration with FDA under its previous tobacco manufacturing status, as of 9/20/2021, and listed as being "out-of-business" (OOB). The firm was found to be in business as a retail vape store providing raw nicotine solution and e-juice components at the retail level. The firm owner, Mr. Aurelius Jeffrey, stated that he inactivated his tobacco registration because he believes his current operations do not meet the legal definition of tobacco manufacturing. The firm's current operation style consists of selling retail customers re-

packaged tobacco nicotine in 10 mL bottles separate from bottles of propylene glycol (PG), vegetable glycerin (VG) and flavors (e-juice). The firm does not wholesale tobacco products. Following the warning letter, the firm discontinued blending and/or mixing tobacco nicotine into the PG/VG, and flavor component blends into a finished tobacco "e-liquid". When retail customers purchase the nicotine and the e-juice flavors, the customers are responsible for mixing/combining the two components. The firm does mix approximately 100 flavors with PG/VG blends. None of the e-liquid/e-juice flavors have been submitted under the Pre-market Tobacco Application (PMTA) process.

The firm sells its products in their retail stores or by phoned-in orders. If by phone order, the firm currently ships nicotine and its e-liquid juice through third-party delivery vendors, such as the U.S. Postal Service, UPS, FedEx, etc. Online purchases have been discontinued according to the firm's website and by Mr. Jeffrey.

The firm's previous operations consisted of blending all e-liquid components where nicotine was combined with the PG/VG and flavors into a finished e-liquid product ready for consumer use. "E-liquids" are consumer products that were deemed as meeting the statutory definition of "tobacco products" under the Federal, Food, Drug & Cosmetic Act, August 8, 2016. This firm is not owned or affiliated with a Native American tribe, and it is not located on tribal land. The firm size is 3.

The inspection consisted of firm operations to include receiving materials, manufacturing/current operations, labeling, distribution/sales, review of records, and standard operating procedures (SOPs). The firm denies that they distribute free samples of their products, and the firm has no plans to attend any public events in the next 12 months.

No samples were collected, and no refusals were noted. Form 463a, Affidavit (**Attachment 1**), was prepared for Mr. Jeffrey. He did not read or sign it due to his company policy and lack of an attorney for legal counsel. The contents of information included in the affidavit were explained to him. At the conclusion of the inspection, no FDA 483, Inspectional Observations, was issued, but several items were discussed and included:

1. The firm no longer blends nicotine into flavored e-liquid bottles, including Soul Vapor Honey Pot and Soul Vapor Peach Rings, and is the reason the firm has not submitted pre-market tobacco applications (PMTA) for any of their flavored e-juices.
2. All of the firm's physical e-juice product labels contain the Nicotine Warning statements.
3. The modified risk tobacco product (MRTP) claims of "All our juices are Diacetyl, Acetyl Propionyl, and Acetoin free!", on the firm's website (www.soulvaporejuice.com), for Soul Vapor Tooty Froots, Soul Vapor Honey Pot, and Soul Vapor Peach Rings flavored e-liquids have been removed.

Mr. Jeffrey stated he plans to continue his current operations of selling nicotine and his e-juices in separate retail units until the FDA provides further notice that he cannot continue his current manner

of operations. Mr. Jeffrey believes that his firm's operations do not meet the standard, legal definition of a "tobacco manufacturer".

I, Investigator McNew (MRM), and Investigator Kim (YK) contributed to the writing of this report. Our initials will correspond to the reported sections of responsibility.

ADMINISTRATIVE DATA
(MRM)

Inspected firm:	Soul Vapor, LLC
Location:	604 Thorn St (frnt) Princeton, WV 24740-3757
Phone:	304-913-4016
FAX:	
Mailing address:	604 Thorn St (frnt) Princeton, WV 24740-3757
Email address:	soulvaporejuice@gmail.com
Dates of inspection:	3/23/2022-3/25/2022
Days in the facility:	3
Participants:	**Matthew R McNew, Investigator - Tobacco Cadre** **Young Kim, Investigator - Tobacco Cadre**

Upon arrival at the firm, I, Investigator McNew, and Investigator Kim, presented our credentials and issued an FDA 482, Notice of Inspection, (**Attachment 2**) to Aurelius Jeffrey (no middle initial), Owner. He identified himself as the most responsible person at the firm. Mr. Jeffrey participated during the inspection and answered questions and provided information. We provided him with the "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)" Guidance for Industry document.

Form 463a, Affidavit **(Attachment 1**), was prepared for Mr. Jeffrey, but he refused to read or sign it citing company policy and lack of legal counsel. He asked what type of information was included and we informed him of the general content within the affidavit.

All FDA correspondence and FMD-145 should be addressed to:
Soul Vapor, LLC
ATTN: Aurelius Jeffrey, Owner
604 Thorn St. (frnt)
Princeton, WV 24740

Website: www.soulvaporjuice.com
Email: soulvaporejuice@gmail.com

HISTORY
(YK)
Mr. Jeffrey stated that the firm's legal name is Soul Vapor, LLC and he is the owner. He stated that the firm opened as an online store in 2015 and recently formed into an LLC in early 2021 in the state of West Virginia. This location is the firm's corporate address and there are no subsidiaries or any affiliated companies. Soul Vapor, LLC operates from 9:00 am to 11:00 pm seven days a week with two (2) full time and two (2) part time employees.

This is the initial inspection of the firm. Soul Vapor, LLC, received a warning letter, dated 5/21/2021 regarding the online sale of tobacco products, specifically two e-liquids products without a marketing authorization order in effect. The firm sent a response to this warning letter on 7/20/2021. The response letter stated that the firm made changes to their website and informed the customers those e-juices were no longer manufactured and not available for purchase.

Neither the firm's finished tobacco products nor the firm itself have been involved in any recalls or market withdrawals.

Soul Vapor, LLC, is currently registered as an "inactive" entity with the FDA. Tobacco manufacturers are required to register under the Federal Food, Drug, and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act. Mr. Jeffrey stated that he changed the firm's registration status to "inactive" on 9/20/2021 since he did not submit PMTAs for his tobacco products and his claims that he has ceased manufacturing tobacco.

INTERSTATE (I.S.) COMMERCE
(YK)
Mr. Jeffrey stated his firm currently manufactures e-juice flavorings without nicotine under the Soul Vapor, LLC brand. Nicotine is purchased from [redacted]; repackaged into 10 ml bottles on-site without further dilution; then sold to the customer. Sometimes the nicotine is sold by itself and other times it is sold with zero nicotine e-juice. He stated that currently 98% of the e-liquid products they produce are sold to retail customers in West Virginia and 2% are shipped via U.S. Postal Service (USPS), or other 3rd party delivery companies, to phone order retail customers into interstate commerce.

According to Mr. Jeffrey, 100% of the ingredients and components used to manufacture their products are sourced from outside the state of West Virginia, including but not limited to NC, CA, AZ, OH, and China. Mr. Jeffrey provided the following incoming ingredient/component and outgoing documentations:

• Invoice #139670 from [redacted], dated May 21, 2019, for [redacted] 250 mg [redacted] Nicotine Salt*-500mg/Proplyne Glycol/250 mg [redacted] from [redacted]. In Thousand Oaks, CA 91320 (**Exhibit 1**).

• Invoice from [redacted], ORDER # 100253359, dated October 29, 2021 for "250 MG NICOTINE LIQUID 250 mg-nicotine-liquid-250 mg-1 gallon-100vg ***250 mg-nicotine-salts-250mg-1 gallon-100vg" from [redacted] in Phoenix, AZ (**Exhibit 2**).

• Order Confirmation #360205, dated March 22, 2022 for multiple flavorings from [redacted] in Morrisville, NC (**Exhibit 3**).

• Purchasing order for Propylene Glycol and Glycerin: Order # 103720510, dated 29th Oct 2021 from [redacted] in Aurora, OH 44202 (**Exhibit 4**).

• Order Number #40763, dated March 18, 2022 for Bullz Eye Size:135 ml Nicotine: 12 mg VG/PG Ratio: 50/VG/50PG (pod devices) shipped to a retail customer in Alderson, WV (**Exhibit 5**).

• Sales Invoice, dated 03/25/2022, timestamp 09:30am, #1, for 120 ml Bottle Big, provided to a retail customer (**Exhibit 6, left receipt**). We observed that a 120 ml bottle of e-liquid blend and a clear bottle with handwritten "3 ml Nicotine" filled with nicotine were sold for this transaction but the receipt only prints "120 ml Bottle Big".

• Sales Invoice, dated 03/25/2022, timestamp 09:36am, #2, for 10 ml Bottle Small (**Exhibit 6, right receipt**). This receipt was created per my request to reflect nicotine sale only. The firm's receipt captures the nicotine sale under the same category as the non-nicotine e-liquid blend sale.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)
(MRM)

The firm first manufactured nicotine e-liquids in November 2015 under the Soul Vapor name. The initial flavors were Blueberry Cheesecake, Sweet Tart, Dreamer's Milk, Banana Pudding, and Strawberry Cheesecake.

See **Exhibit 7** for the firm's current list of e-juice flavored products, not containing nicotine. Mr. Jeffrey annotated the list with "CA" for those flavored juices that contain citric acid. He stated that the citric acid is added to those juices that have a fruit profile flavor. The list also indicates which flavors are currently discontinued.

A representative label of the Divinity flavor is attached as **Exhibit 13, photo 1**.

Currently, the firm does not anticipate the manufacture of any new tobacco products into U.S. commerce.

(YK)

Soul Vapor, LLC, is currently a manufacturer and a retail distributor of non-nicotine e-juices for use in electronic nicotine delivery systems (ENDS) products. The firm also repacks and distributes nicotine separately.

The firm does not manufacture in bulk quantities, and it fills all its non-nicotine e-juice products and nicotine into plastic bottles with child resistant bottle caps. All non-nicotine e-juices are currently produced under the brand name Soul Vapor.

Mr. Jeffrey stated that the firm manufactures approximately 100 different e-juice flavors with a 70/30 PG/VG blend in 10 ml, 30ml, and 120 ml bottles. A separate bottle of nicotine is provided per customer's request, ranging from 3 mg nicotine, 6 mg nicotine, 12 mg nicotine, 18 mg nicotine, and 24 mg nicotine by formulated weight. E-liquids utilizing salt-nicotine are referred to as "Salted" products and are distributed with levels of salt-nicotine ranging from 25 mg, 35 mg, 50 mg, 60 mg, and 70 mg salt-nicotine by formulated weight.

Mr. Jeffrey provided labels for Soul Vapor Peach Rings, Honey Pot, Tooty Froots, and Zebra Blood e-liquid **(Exhibit 8)** and are top sellers. He stated that these labels are applied on the non-nicotine e-juice blends and uses labeling with the nicotine warning statement.

Mr. Jeffrey said he currently has no definitive plans to attend any trade shows. He said the firm does not provide any free samples to customers. Mr. Jeffrey said that the firm's product marketing consists of social media marketing (i.e.- Instagram, Tweeter, Pinterest, YouTube and Facebook) and the brand website www.soulvaporejuice.com.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

(MRM)

The following individuals participated and/or provided information during the inspection:

- **Aurelius Jeffrey (NMI), Owner**, is the most responsible person of the firm and oversees all business aspects. He has the authority to correct, detect, and prevent issues pertaining to the firm. His duties include, but not limited to, order and receipt of components and materials, finances, manufacturing, and the selling of tobacco related products. He makes all decisions for and has final authority of his business.
- **Leslie Beasley, Retail Store Clerk,** is Mr. Jeffrey's spouse and conducts business and sales transactions in the front retail store. She was observed helping customers and making retail sales during the inspection. She answered questions pertaining to product retail sales.

FIRM'S TRAINING PROGRAM

(YK)

The firm has no written training procedures and does not document training of employees. Mr. Jeffrey explained that employees mainly receive job-specific trainings for approximately 2 weeks and the training is performed via on-the-job by him and/or Ms. Leslie Beasley.

MANUFACTURING/DESIGN OPERATIONS

(MRM)
The firm's current operations consist of selling 250 mg/ml of nicotine/vegetable glycerin and/or 250 mg/ml of nicotine salts/vegetable glycerin solutions from bulk containers (one- or five-gallon size) into a 10 ml container, without further dilution, and a PG/VG/flavor blend e-juice into a separate bottle. The current inventory, of nicotine or e-juice products, has not been submitted under a PMTA.

The firm only produces its private line of e-juices under the Soul Vapor label. The firm does not keep or maintain production records. The firm's line of e-juice products is usually produced by Mr. Jeffrey. The nicotine is transferred from the bulk containers into a 16 oz. plastic squeeze bottle and then into 10 mL bottles, and handwritten labeled with "Nicotine, X ml", where "X" is the volume of nicotine filled. We observed a bottle stating, "nicotine, 3 ml".

The firm does not have manufacturing quality procedures, but Mr. Jeffrey stated that e-juice consistency, flavor, and impurity checks are conducted by visual and organoleptic methods prior to filling bottles. Once the e-juice bottles are filled, labels are placed onto the bottles. The firm has an inventory of e-juices and they are displayed on the retail store shelves. **Exhibit 13, photos 2 and 3**, are photographs of e-juice inventory.

These separate bottled products are sold at retail. Customers may purchase nicotine separately, e-juices separately, or they may purchase nicotine and e-juice bottles during the same transaction. Mr. Jeffrey stated that nicotine is always sold in 10 mL bottles. All other size bottles are e-juices.

Once the customer orders and purchases the nicotine and e-juice, the products are later blended by the customer. Retail employees only provide verbal instructions to the customer on properly mixing the nicotine with the flavored e-juice. The firm does not have or provide written instructions. Customers are informed to empty all of the nicotine into their bottle of flavored e-juice and shake the combined bottle to mix. The customer will then add the e-liquid into the tank of their vaping device.

Mr. Jeffrey stated that they initially instruct new customers on this method, but the established customers who have been vaping for some time know and understand how to properly mix the components together. Mr. Jeffrey stated that his customers are informed of and know that they must mix the nicotine with the e-juice blend and that they cannot vape the nicotine in its purchased form alone.

<u>Nicotine products</u>
The firm receives a pre-blend of nicotine/VG in either one- or five-gallon containers. Nicotine is purchased in 250 mg/mL nicotine/vegetable glycerin solution or 250 mg/mL salt nicotine/vegetable glycerin solution directly from the supplier. See **Exhibit 13, photos 4 and 5**, for photograph labels for [redacted] and [redacted] and **Exhibits 1 and 2** for the previous purchase of nicotine on invoices #139670 and #100253359.

Nicotine suppliers:

- [redacted] (previously known as [redacted] (FEI #3013538145), [redacted] Thousand Oaks, CA 91320
- [redacted] (FEI # 3013036573), [redacted] Phoenix, AZ 85034

The firm receives their 10 mL bottles, used for nicotine, from [redacted], China. Mr. Jeffrey stated that he orders these from the Alibaba.com website. We collected an email order confirmation, 12/25/21, #125969966001026250, for the order of 1500, 10 mL bottles, and it is attached as **Exhibit 9**.

The firm does not produce tobacco products with synthetic nicotine. No synthetic nicotine was observed during the inspection.

Propylene glycol and vegetable glycerin products

Propylene glycol (PG) and vegetable glycerin (VG) are purchased in one- or five-gallon containers. The firm receives their PG and VG from [redacted] (FEI# 1520307), [redacted] Aurora, OH 44202.

See **Exhibit 13, photos 6 and 7** for PG and VG labeling photographs. Refer to **Exhibit 4** for the previous invoice order #103720510, 10/29/21, for these products, and see **Exhibit 10** for representative product data and specification sheets/Certificate of Analysis (COA) of PG and VG.

Flavors

The firm receives their flavors, in various sizes, from [redacted], Morrisville, NC. See **Exhibit 3** for the previous purchase invoice #360205, 3/22/22. Currently, the firm has approximately 100 flavors in their product list.

Current manufacturing/production operations

The firm does not conduct testing on incoming raw materials. Only the certificate of analysis is referenced. Mr. Jeffrey has not conducted any validation tests on his production methods. The firm previously manufactured finished nicotine blended e-liquids for online and retail store customers but ceased this method of operations following their 5/21/21 warning letter from the FDA. Mr. Jeffrey stated that he stopped manufacturing finished e-liquids about eight months ago and last wholesaled his products about one year ago. Following this transition, he began his current operations of separating the nicotine and flavored e-liquids and selling these two components at retail from his store.

The firm produces e-juices by its formulations. All batches consist of blending a 70 VG/30 PG ratio by weighing these components, and depending on the flavor, an 18%-24% flavor is added to complete the e-juice.

Nicotine is measured by Mr. Jeffrey's formulated weights depending on the strength ordered by the customer. Mr. Jeffrey only provided that he weighs the levels for nicotine strength levels, and did not provide his equation formulations. He provided examples such as a 4% nicotine level is approximately equivalent to 35 mg, 5% nicotine to 50 mg, and 6% to 60 mg. Mr. Jeffrey stated that 3 mg of nicotine in a 120 mL e-juice will contain approximately 1.72 g of nicotine. A 6 mg strength in a 120 mL e-juice will contain approximately 3.45 g of nicotine.

To fill a nicotine order, the raw nicotine solution is transferred into a 16 oz. squeeze bottle for easier handling and order fulfillment. When a customer orders a specific nicotine strength, an employee fills the 10 mL bottle on the scale and weighs out the nicotine to the strength level required according to their conversion factor. The greater the nicotine concentration, the more nicotine volume is added into the customer bottle, based on the firm's formulation. Formulations were not provided. **Exhibit 13, photos 8 and 9**, are empty 10 mL retail bottles used for nicotine.

The firm uses calibrated scales to weigh ingredient products. Mr. Jeffrey stated that he has two scales and that they are calibrated by a 3rd party every two years. One scale is located in the production area in the back of the store, and the other one is in the front retail area. The retail scale was calibrated three months ago. The production scale is less than two years old and is calibrated. He stated that he conducts monthly weight scale checks by using verified 5-, 10-, and 15-gram weights.

Once a batch of e-juice is produced the inventory is placed on the retail store shelves for sale. The retail store does not display public pricing for nicotine or e-juice bottles. The only pricing observed in the store was a special closeout pricing on e-juice and salt nicotine. These prices reflect the cost of e-juices and nicotine when purchased together. See **Exhibit 13, photo 10**, for a photo of the price display. The retail area provides a product e-juice flavor list for customers to choose their flavor for purchase.

Mr. Jeffrey provided two customer receipts showing how products are listed in the record system (refer to **Exhibit 6**). Nicotine and e-juice receipts only show the quantity size of the bottle sold and not a description of the specific product sold for nicotine and e-juices.

Customers can also order products by phone. Customers visit the firm's website and call the store to fill the order. Mr. Jeffrey stated that he or his staff require a picture identification, for age verification, usually received by cell phone text messaging. Once the identification is received and verified that the customer is at least 21 years of age, the order is filled, and then the product is shipped by U.S. Postal Service or another 3rd party delivery company. Refer to **Exhibit 5** for the last customer phoned order shipment, order #40763, 3/18/22, and **Exhibit 11** for the last online purchase

for interstate order #40357, 5/3/21 from Soul Vapor, Princeton, WV, to a customer located in North Brookfield, MA.

Mr. Jeffrey provided a 3/20-25/22 sales log of e-liquids sold (**Exhibit 12**). The Soul Vapor "Store Statistics" document lists the sales of 61 bottles only as "E-liquid". This report log combines sales of e-juice and nicotine bottles under this category. The software program does not breakdown sales further than this general category.

MANUFACTURING CODES
(YK)
Mr. Jeffrey stated that the firm does not apply any manufacturing codes or "best by dates" on their non-nicotine e-juice and repackaged nicotine products.

COMPLAINTS
(YK)
The firm does not maintain written procedures for consumer complaints nor maintains a complaint log. I asked Mr. Jeffrey if they have received any adverse or health related complaints with their products, including but not limited to, allergic reactions, seizures, hives, or other health related issues. He stated they have not received any health-related complaints or adverse reactions.

RECALL PROCEDURES
(YK)
The firm has no written recall procedure established. Per Mr. Jeffrey, the firm has not conducted any recalls or market withdrawals of any of their products since the firm was formed in 2015. Mr. Jeffrey stated that in the case of any recall, he would remove all affected products from the retail shelf and notify customers who may have purchased the affected product.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE
(MRM)
An FDA 483, Inspectional Observations, was not issued at the closeout meeting.

REFUSALS
(MRM)
No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT
(MRM)
Prior to closeout, Form 463a, Affidavit, was prepared for Mr. Jeffrey, but he refused to read or sign it citing company policy and lack of legal counsel. He declined that the affidavit be read to him, but

he stated that we could verbally provide him the general contents that were included in the affidavit. We stated the general content outlined in the affidavit.

During the closeout, we met with Mr. Aurelius Jeffrey, Owner. No FDA 483, Inspectional Observations, was issued. Items discussed included the following:

1. The firm no longer blends nicotine into any flavored e-juice bottles, including Soul Vapor Honey Pot and Soul Vapor Peach Rings. Because Mr. Jeffrey changed his manufacturing operation methods, this is the reason the firm has not submitted pre-market tobacco applications (PMTA) for any of their flavored e-juices.
2. All of the firm's e-juice product labels contain the Nicotine Warning statement.
3. The modified risk tobacco product (MRTP) claims of "All our juices are Diacetyl, Acetyl Propionyl, and Acetoin free!", on the firm's website (www.soulvaporejuice.com), for Soul Vapor Tooty Froots, Soul Vapor Honey Pot, and Soul Vapor Peach Rings flavored e-liquids have been removed.

Mr. Jeffrey has ceased combining nicotine into his flavored e-juices and has since changed operations to only blend VG/PG/flavoring into one bottle and repack nicotine into a separate 10 ml bottle. Mr. Jeffrey stated that he plans to continue his current operations until the FDA provides further notice that he cannot continue his current manner of operations. He stated that he does not believe that his firm's production methods meet the standard, legal definition of a "tobacco manufacturer" and because he does not produce a "finished" tobacco product. This is the reason that he doesn't believe that he needed to submit his list of e-juice products in a PMTA.

Mr. Jeffrey was reminded to comply with the FD&C Act. Penalties for non-compliance may include, but not limited to, warning letters, seizures, injunctions, monetary penalties, and prosecution.

SAMPLES COLLECTED
(MRM)
No samples were collected during the inspection.

VOLUNTARY CORRECTIONS
(MRM)
The firm received a warning letter, dated 5/21/2021, for marketing Soul Vapor Honey Pot and Soul Vapor Peach Rings, deemed as new tobacco products, because they were not commercially marketed in the United States as of February 15, 2007, and did not have an FDA marketing authorization.

Mr. Jeffrey stated that he believed this issue to be resolved since he no longer "manufactures" these products because he stopped combining/mixing/blending nicotine into flavored e-juices. He ascribes that since he does not meet the technical definition of a "tobacco manufacturer" that he has corrected this issue. He has separated the production process and sells raw nicotine and the flavors in two

separate containers for customers to blend after they purchase the products and believes that he has resolved the marketing authorization issue.

The firm also corrected other Center for Tobacco (CTP) concerns including tobacco products that had modified risk claims of "All our juices are Diacetyl, Acetyl Propionyl, and Acetoin free!", on the firm's website (www.soulvaporejuice.com), for Soul Vapor Tooty Froots, Soul Vapor Honey Pot, and Soul Vapor Peach Rings flavored e-liquids. As of on/about 3/24/22, Mr. Jeffrey removed this claim for all flavored e-juice products advertised on this website.

The officially sealed original copy compact disc (CD) containing the electronic records, provided by the firm during the inspection, are filed with the unlabeled exhibits and attachments.

EXHIBITS COLLECTED

1. EX Invoice #139670 from [redacted], 5/21/19 (1 pg)
2. EX Invoice #100253359 from [redacted], 10/29/21 (2 pg)
3. EX Invoice #360205, [redacted], 3/22/22 (2 pg)
4. EX Invoice #103720510, [redacted] Propylene Glycol and Glycerin, 10/29/21 (5 pg)
5. EX Phoned customer order invoice #40763 for 135 ml bottle Bullz Eye e-juice, VG/PG Ratio: 50/VG/50PG (pod devices), and 12 mg nicotine, 3/18/22 (1 pg)
6. EX Sales invoice receipt, timestamp 09:36am, #2, 10 ml Bottle Small, 3/25/22 (1 pg)
7. EX Annotated current list of Soul Vapor e-juice flavored products (4 pg)
8. EX Soul Vapor Honey Pot, Peach Rings, Tooty Froots, and Zebra Blood e-juice labeling (1 pg)
9. EX Email order confirmation #125969966001026250, for 10 mL bottles, 12/25/21 (1 pg)
10. EX Order #103720510 and representative product data and specification sheets/Certificate of Analysis (COA) of propylene glycol and vegetable glycerin (glycerin), 10/29/21 (5 pg)
11. EX Online interstate purchase order #40357, 5/3/21 (1 pg)
12. EX Soul Vapor "Store Statistics" sales log of e-liquids sold for dates of 3/20-25/22 (1 pg)
13. EX Inspectional photographs (5 pg)

ATTACHMENTS

1. ATT FDA Form 463a, Affidavit, unsigned (2 pg)
2. ATT FDA Form 482, Notice of Inspection (3 pg)
3. ATT Inspection Assignment Memorandum, Directed Inspection Request, 3/4/22 (17 pg)

Matthew R. Mcnew -S
Digitally signed by Matthew R. Mcnew -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300226994, cn=Matthew R. Mcnew -S
Date: 2022.04.05 16:16 30 -04'00'

Matthew R. McNew, Investigator
ORA/OMPTO/TOS

Young Kim -S
Digitally signed by Young Kim -S
Date: 2022.04.05 18:56:44 -04'00'

Young Kim, Investigator
ORA/OMPTO/TOS

EXHIBIT B

B-2 McNew Exhibit

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
8100 NW 67th St #400
Miami Lakes, FL 33014
305-526-1475

TO

2. NAME AND TITLE OF INDIVIDUAL
Aurelius Jeffrey, Owner

3. DATE
3/23/22

4. FIRM NAME
Soul Vapor LLC

5. HOUR
9:48 a.m.
p.m.

6. NUMBER AND STREET
604 Thorn St.

7. CITY AND STATE & ZIP CODE
Princeton, WV 24740

8. PHONE NO. & AREA CODE
304-913-4016

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
	Young Kim, Investigator

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation

(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

EXHIBIT B

B-3 McNew Exhibit (Customer Sales Invoice)

604 Thorn St.
Princeton, WV 24740

Billing Address

[redacted]
alderson, WV 24910

Shipping Address

[redacted]
alderson, WV 24910

Invoice

Order Number	40763
Order Date	March 18, 2022
Payment Method	Authorize.net
Email	[redacted]
Telephone	[redacted]

Product	Price	Quantity	Total
Bullz Eye Size:135ml Nicotine:12mg VG/PG Ratio:50VG/50PG (pod devices)	$25.00	1	$25.00
Subtotal			**$25.00**
Shipping			$5.47 via First Class Mail
Tax			$1.50
Total		1	**$31.97**

Thank you for your order!

soulvaporejuice@gmail.com
(304)913-4016
(304)320-6019

EXHIBIT B

B-4 McNew Exhibit (Customer Sales Invoice)

SOUL VAPOR
604 Thorn St
Princeton, WV 24740
(304) 913-4016

SALES INVOICE

Geek Vape Supermesh X2 Coil .4ohm	19.99 T
120ml Bottle Big	25.00 T
Subtotal	44.99
Tax	3.15
Total Sale	**$ 48.14**
Credit/Debit	48.14
Change	0.00

VISA CREDIT [redacted]
Auth Code: [redacted]
Entry Type:
AID:
ARQC:
ECRID:

Sold Items : 2
Verified Age : 21

Thank you for shopping at our store! Our goal is your satisfaction every time you shop with us.

Vape The FINE

Please tell us your BOSS Revolution number with every order to receive BR Club benefits.

Visit:BRCLUBSAVES.COM

****
===== Rewards for BR #: 3048889059 =====
****
* Store Club: Buy 20 120ml Bottles get one FREE!
*
* Earned now: 0 Free items, 1 star *
* Current: 0 Free items, 6 stars *
* Next Free item in: 14 more stars *
****
* Store Club: Buy 20 Packs of Coils Get 1 FREE!
*
* Earned now: 0 Free items, 1 star *
* Current: 0 Free items, 2 stars *
* Next Free item in: 18 more stars *
****

Your Cashier : Leslie Jeffrey
Terminal: 23253

03/25/2022 09:30am, #1

SOUL VAPOR
604 Thorn St
Princeton, WV 24740
(304) 913-4016

SALES INVOICE

10ml Bottle Small	4.00 T
Subtotal	4.00
Tax	0.28
Total Sale	**$ 4.28**
Cash	4.28
Change	0.00

Sold Items : 1
Verified Age : 21

Thank you for shopping at our store! Our goal is your satisfaction every time you shop with us.

Vape The FINE

Please tell us your BOSS Revolution number with every order to receive BR Club benefits.

Visit:BRCLUBSAVES.COM

Your Cashier : Leslie Jeffrey
Terminal: 23253

03/25/2022 09:36am, #2

EXHIBIT B

B-5 McNew Exhibit (Flavor List)

SOUL VAPOR FLAVOR LIST

*Angel Breath (discontinued)

CA Angry Bear

Bad Apples

CA Banana Apple Cream

Banana Ice Cream

Banana Pudding

CA Beetlejuice

CA Blood Dragon

CA Blue Ballz

CA Blue Blood Moon

Blue Monster

Blueberry Cheesecake

*Blueberry Jammy (discontinued)

CA Bomb-Ade

*Bon Bon (discontinued)

Bubbleberry

CA Bubblegrape

CA Bubblemelon

Bucks Blend

CA Bullz Eye CA

CA Butter Cake

Butterscotch

CA Campfire S'mores

Candy Cane

CA Candy Fish

Caraccino

CA Caramel Apple

*Cat's Pajamas (discontinued)

*Chai Tea (discontinued)

*Cherry Cheesecake (discontinued)

*Classic Crush (discontinued)

Classic Lights

Classic Menthols

Classic Reds

Coconut Cream

Cookies N' Cream

Cool Passion

Cool Waters

Cotton Candy

Coven

Crispy Cakes

*Divinity (discontinued)

Dr. Pecker

Dream Cream

Dreamers Milk

Endless Summer

Fuji Apple Dream

Gloom Lagoon

Grape-A-Berry

Green Monster

Honey Grahams

Honey Pot

Hot Sauce

Iced Strawberry

Just Berries

Just Mint

Kamikaze

Key Lime Pie

*Kings Brew (discontinued)

Lemon Cookie

Lola Cherry Cola

Lovers Milk

CA Mango Melons

CA Mango Tango

*Mint Fudge Brownie (discontinued)

CA Monkey Bread

CA Monster Mango

Moon Milk

*Paisley Lynn (discontinued)

*PB Cereal (discontinued)

CA *PB&J Grahams (discontinued)

CA Peach Berry

CA Peach Rings

Peanut Butter Pie

Pina Colada

CA Pineapple Grapefruit

CA Pineapple Rings

Pink Monster

CA P.M.S. (Peach Mango Strawberry)

CA Pomedragon

CA Princeton Dew

Princeton Pride

Pumpkin Spice

Pure Rum

Purple Daze

CA Razzled

*Red Licorice (discontinued)

Red Velvet Cake

Root Beer Float

Sanguine Nectar

Scaredy Cat

Snake Venom

CA Snow Dragon

Strawberry Cheesecake

Strawberry Shortcake

Strawberry Taffy

Strawnana

Sucker Punch

*Sun Tears (discounted)

Surf Sauce

Sweet Tart

Sweet Tea

The 'Brina

Tigers Blood

Tooty Froots

Top Shelf

Turkish Shisha

Twisted Lemon

Unicorn Poop

Vanilla Caramel

Watermelon Lime

*White Coconut Cake (discontinued)

White Flame

Zebra Blood

Zombie Blood

EXHIBIT B

B-6 McNew Exhibit (EIR Photographs)

Photo 1: Photograph of a representative label for Soul Vapor e-juices.

Photo 2: Photograph of retail inventory e-juice bottle display consisting of various sizes including 30 and/or 120 mL sizes.

Photo 3: Photograph of retail inventory e-juice display consisting of 10 mL size bottles.

Photo 4: Photograph of the nicotine label product that is sold in 10 mL retail bottles.

Photo 5: Photograph of a second nicotine label product that is sold in 10 mL retail bottles.

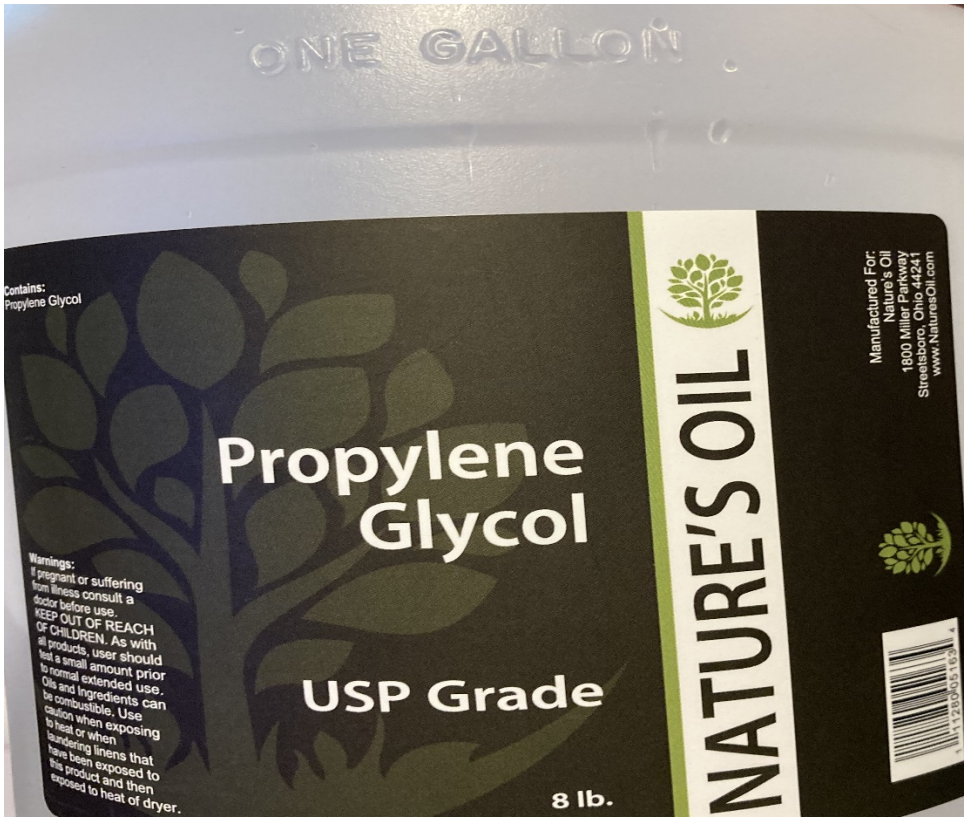

Photo 6: Photograph of the propylene glycol label product that is added to e-juice.

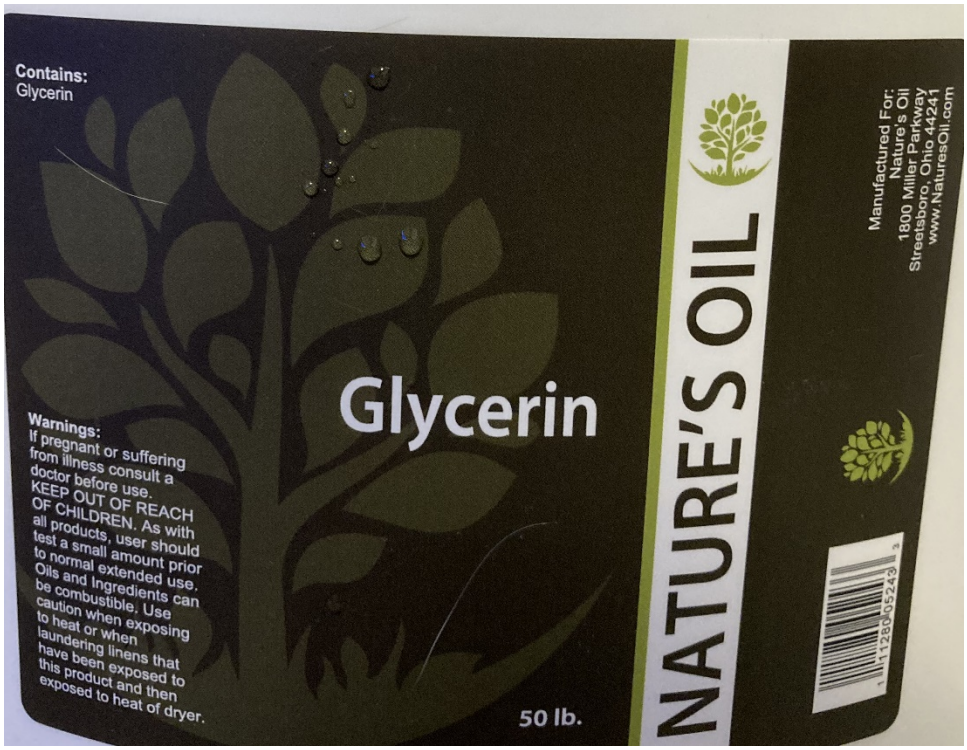

Photo 7: Photograph of the vegetable glycerin label product that is added to e-juice.

Photo 8: Photograph of a dark 10 mL bottle used to hold a customer's nicotine.

Photo 9: Photograph of a clear 10 mL bottle, with cap, used to hold a customer's nicotine.

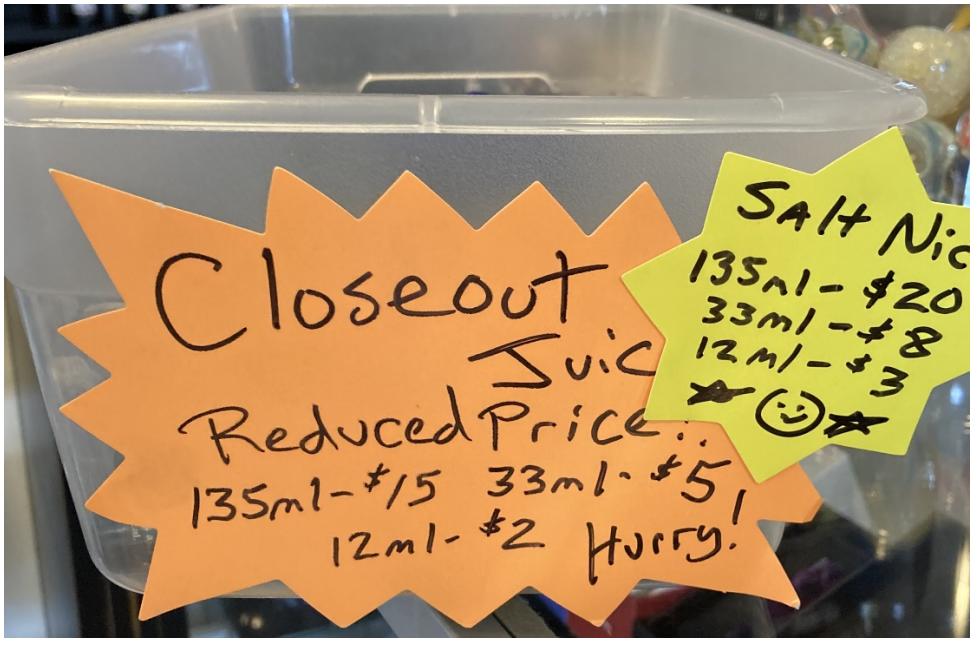

Photo 10: Photograph of retail closeout pricing on e-juice and salt nicotine.

EXHIBIT B

B-7 McNew Exhibit (Nicotine Invoice)

[redacted]

INVOICE

May 21, 2019

Bill to

Aurelius Jeffrey
Soul Vapor
604 Thorn Street
Soul Vapor Store Front
Princeton, WV 24740
Tel: 3043206019

Ship to

Aurelius Jeffrey
Soul Vapor
604 Thorn Street
Soul Vapor Store Front
Princeton, WV 24740
Tel: 3043206019

Invoice **#139670**

Payment: [redacted]
Shipping: Free Shipping
Email: aureliusjeffrey@yahoo.com

Item	Qty	Price	Item Total
[redacted] 250mg [redacted] Nicotine Salts* - 500ml / Propylene Glycol / 250mg [redacted]	× 1	$79.99	$79.99

Notes

Product warnings: 131521904654
Checkout alerts: 161

Sub-total	$79.99
Shipping	$0.00
Total	**$79.99**

Thank You For Your Business!

[redacted]

Soul Vapor, LLC FEI# 3014759057
3/23-25/22 MRM, YK
Exhibit 1, Page 1 of 1

EXHIBIT B

B-8 McNew Exhibit (Nicotine Invoice)

[redacted]

ORDER #100253359

ORDER DATE: OCTOBER 29, 2021

SHIPPING ADDRESS

Aurelius Jeffrey
Soul Vapor
604 Thorn St. FRNT
Princeton, West Virginia, 24740
United States
T: 3043206019

BILLING ADDRESS

Aurelius Jeffrey
Soul Vapor
604 Thorn St. FRNT
Princeton, West Virginia, 24740
United States
T: 3043206019

SHIPPING METHOD

Freight (Commercial Addresses Only) - R & L Carriers Inc

PAYMENT METHOD

Credit Card (Authorize.net)
Credit Card Type: [redacted]
Credit Card Number:
Processed Amount: $2,661.67

ITEMS ORDERED

PRODUCT NAME	SKU	PRICE	QTY	SUBTOTAL
250MG NICOTINE LIQUID ***Nicotine Content (mg/mL):*** 250mg ***Volume:*** 1 Gallon ***Base:*** 100VG	250mg-nicotine-liquid-250mg-1gallon-100vg	$399.99	Ordered: 5 Shipped: 5	$1,999.95

Subtotal	$2,469.94
Shipping & Handling	$191.73
Grand Total	**$2,661.67**

[redacted]

Print Order #109253359

PRODUCT NAME	SKU	PRICE	QTY	SUBTOTAL
250MG NICOTINE SALTS ***Nicotine Content (mg/mL):*** 250mg ***Bottle Size:*** 1 Gallon ***Base:*** 100VG	250mg-nicotine-salts-250mg-1gallon-100vg	$469.99	Ordered: 1 Shipped: 1	$469.99

Subtotal	$2,469.94
Shipping & Handling	$191.73
Grand Total	**$2,661.67**

CLOSE WINDOW

[redacted]

EXHIBIT B

B-9 McNew Exhibit (PG VG Invoice)

[redacted]

15% off | orders over $250 use code - 15off250

Search the store

Home / Your Account / Your Orders / Order #103720510

Order #103720510

Order Contents

2 × Propylene Glycol $153.97

Size: 40 lb ($3.88 / lb) - $153.97

1 × Glycerin $1,093.90

Size: 551 lb drum *** $1.69 / lb or $929.81

Subtotal: $1,401.84

Coupon Code (15off250): -$210.28

[redacted]

Soul Vapor, LLC FEI# 3014759057
3/23-25/22 MRM, YK
Exhibit 4, Page 1 of 5

Shipping:	$227.90
Tax:	$99.37
Grand Total:	$1,518.83

Order Details

Order status: Shipped
Order date: 29th Oct 2021
Order total: $1,518.83
Payment method: Credit Card

Print Invoice

Ship To

Aurelius Jeffrey
Soul Vapor
604 Thorn St FRNT
Soul Vapor Storefront
Princeton, West Virginia 24740-3757
United States

Bill To

Aurelius Jeffrey
Soul Vapor
604 Thorn St FRNT
Soul Vapor Storefront
ton, West Virginia 24740-3757
U..ed States

[redacted]

Shipping Details

Date Shipped: 9th Nov 2021
Shipping Method: Other
Tracking Link: 95090859-9 R+L — LTL Quote (If shipping to a residential address or liftgate required contact us) (LTL)

Actions

Reorder Return

[redacted]

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[redacted]

[redacted]

15% off | orders over $250 use code - 15off250

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[redacted]

Monday-Friday from 8:30 A.M. - 4:30 P.M. EST

For customer support, please email us at:

[redacted]

For regulatory documents, please email us at:

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Aurora, Ohio 44202

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